UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,699	02/19/2002	Charles A. Nicolette	GZ 2104.20	9899

30089 7590 03/18/2005

GENZYME CORPORATION C/O BINGHAM MCCUTCHEN
BINGHAM MCCUTCHEN, LLP
SAN FRANCISCO, CA 94111

EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/079,699	NICOLETTE, CHARLES A.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-6, 13, 15, and 19-21, drawn to methods for determining the amount of PAR-3 protein in a sample, comprising detecting the amount of mRNA transcribing PAR3 protein, classified in class 435, subclass 6.

II. Claims 9, 10, 17 and 18, drawn to methods for determining the amount of PAR-3 protein in a sample, comprising detecting the amount of protein using an antibody that binds to PAR-3, classified in class 435, subclass 7.1.

III. Claims 11 and 12, drawn to methods for determining the amount of PAR-3 protein in a sample, comprising detecting the amount of protein using a cell that binds to PAR-3, classified in class 435, subclass 4, class 436, subclass 503.

IV. Claims 22-26, drawn to a kit comprising an agent or an antibody that binds to PAR-3, classified in class 530, subclass 387.1.

V. Claim 27, drawn to a kit comprising a probe or primer that binds to mRNA encoding PAR-3 protein, classified in class 536, subclass 24.3.

VI. Claims 28 and 29, drawn to an assay to screen for agents that modulate the binding of PAR-3 to its ligand, classified in class 435, subclass 4.

2. Claim 8 links inventions II-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claim 8. Upon the allowance of the linking

claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicant is advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims in the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 1, 7, 14 and 16 link inventions I, II and III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1, 7, 14 and 16. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicant is advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims in the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The inventions are distinct, each from the other, for the following reasons:

Inventions IV and V are patentably distinct products.

The agents or antibody of group IV and polynucleotide of group V are patentably distinct inventions for the following reasons. The antibody of group IV includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group IV which are composed of amino acids, and polynucleotides, such as the probes and primers of group V which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group V will not encode an antibody of group IV, and the antibody of group IV cannot be encoded by a polynucleotide of group V. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group IV and group V would impose a serious search burden since a search of the polynucleotide of group V is would not be used to determine the patentability of an antibody of group IV, and vice-versa.

Inventions I, II, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of

determining the amount of PAR-3 expression comprising detecting the amount of mRNA encoding PAR-3 protein (group I), method of determining the amount of PAR-3 expression comprising detecting amounts of PAR-3 protein using an antibody (group II), and the method of determining the amount of PAR-3 expression comprising detecting the amount of PAR-3 protein using a cell that binds to PAR-3 (group III) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for diagnosis of the autoimmune disease differ significantly for each of the materials. For detection of PAR-3 expression using a polynucleotide, hybridization methods are used, and the degree to which mRNA is expressed is detected. For detection of PAR-3 expression using an antibody, quantitation of labeled antibody may be used and the amount of PAR-3 protein is measured. For detection of PAR-3 expression using a cell that binds to PAR-3, a cell is used instead of an antibody and the amount of PAR-3 is measured. Therefore, each method is divergent in materials and steps. For these reasons the Inventions I, II and III are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I, II and III have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I, II and III together.

Inventions VI and any of I, II or III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. Invention VI, drawn to an assay to screen for agents that modulate the binding of PAR-3 to its ligand is unrelated to any of inventions I, II or III, which are each drawn to various methods for detecting and quantitating PAR-3 expression. The method of invention VI is drawn to methods of screening for agents that modulate binding of PAR-3 to its ligand, comprising the use PAR-3 protein and its ligand to detect any change in binding in the presence of a test agent. Therefore, the inventions of group VI requires different steps and uses different materials. For these reasons the Inventions, I, II, III and IV are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I, II, III and IV have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I, II, III and IV together.

Inventions IV and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of group IV can be used for the purpose of purifying PAR-3 protein from a mixuture or proteins.

Searching the inventions of Groups IV and II together would impose serious search burden. The inventions of Groups IV and II have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the searches for the antibodies and the method of determining the amount of PAR-3 expression are not coextensive. Group IV encompasses a search for antibodies that may bind to any epitope of PAR-3 and may be used in other methods, such as a methods of protein purification or a methods of treatment, which is a search that is not required for a search of group II.

Inventions V and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides of group V (the term "probe" or "primer" is interpreted as an intended use clause) can be used for the purpose of making a recombinant PAR-3 protein.

Searching the inventions of Groups V and I together would impose serious search burden. The inventions of Groups V and I have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the searches for the polynucleotides and the method of determining the amount of PAR-3 expression are not coextensive. Group V encompasses a search for polynucleotides and may be used in other methods, which is a search that is not required for a search of group I.

Inventions VI and either IV or V are unrelated because the products of either of groups IV or V are not used or otherwise involved in the process of group VI.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate

in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
March 14, 2005

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
3/14/2005